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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/002,669

10/31/2001

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11738.00046

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27581 7590 06/03/2009  
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EXAMINER

NAJARIAN, LENA

ART UNIT

PAPER NUMBER

3686

MAIL DATE

DELIVERY MODE

06/03/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/002,669  
Filing Date: October 31, 2001  
Appellant(s): HARTLAUB, JEROME T.

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Robert H. Resis  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 3/24/09 appealing from the Office action mailed 10/10/08.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

A substantially correct copy of appealed claims 12-26 and 39-48 appears on pages A1-A8 of the Appendix to the appellant's brief. The minor errors are as follows: the status of the claims has not been identified.

**(8) Evidence Relied Upon**

US 2002/0016568 A1	LEBEL et al.	2-2002
4,766,542	PILARCZYK	8-1988
US 2002/0010597 A1	MAYER et al.	1-2002
6,112,182	AKERS et al.	8-2000
6,345,260	CUMMINGS, Jr. et al.	2-2002

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-15, 17-26, 39 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al. (US 2002/0016568 A1) in view of Pilarczyk (4,766,542).

(A) Referring to claim 12, Lebel discloses an implantable drug delivery device for delivering at least one drug to a patient comprising in combination (abstract of Lebel):

(a) at least one reservoir each containing at least one drug (para. 60 of Lebel);

(b) a drug scheduling module for determining whether the drug should be replenished (para. 179 of Lebel); and

(d) a telemetry module providing bi-directional communications with an external device (Fig. 3 of Lebel),

wherein the drug scheduling module receives data about the implantable drug delivery device, wherein the data is drug usage information (para. 179 and para. 180 of Lebel).

Lebel does not disclose an appointment scheduling module automatically initiated by the drug scheduling module, and without scheduling input contemporaneously provided by the patient, for automatically scheduling an appointment to replenish the drug in the device and allowing the appointment scheduling module to schedule the appointment.

Pilarczyk discloses an appointment scheduling module automatically initiated by the drug scheduling module, and without scheduling input contemporaneously provided by the patient, for automatically scheduling an appointment to replenish the drug in the device and allowing the appointment scheduling module to schedule the appointment (col. 1, line 52 – col. 2, line 34 and col. 6, lines 15-55 of Pilarczyk).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Pilarczyk within Lebel. The motivation for doing so would have been to automatically identify a refill date in order for

replenishment to occur when the customer's supply of the drug runs out (col. 1, line 52 – col. 2, line 34 of Pilarczyk).

Insofar as the claim recites “selected from the group consisting of,” it is immaterial whether or not the other elements are also disclosed.

(B) Referring to claim 13, Lebel discloses wherein the module contacts via the external device at least one entity, wherein the entity is selected from the group consisting of a pharmacy, a caregiver, a physician, a hospital, and the patient (para. 134 of Lebel).

Lebel does not expressly disclose an appointment scheduling module.

Pilarczyk discloses an appointment scheduling module (col. 1, line 52 – col. 2, line 34 and col. 6, lines 15-55 of Pilarczyk).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Pilarczyk within Lebel. The motivation for doing so would have been to automatically identify a refill date in order for replenishment to occur when the customer's supply of the drug runs out (col. 1, line 52 – col. 2, line 34 of Pilarczyk).

(C) Referring to claim 14, Lebel discloses the drug scheduling module further receives data (para. 320 of Lebel).

(D) Referring to claim 15, Lebel discloses wherein the drug management instructions is deliver drug to a specified location (para. 204 of Lebel).

Insofar as the claim recites “the group consisting of,” it is immaterial whether or not the other elements are also disclosed.

(E) Referring to claim 17, Lebel discloses wherein the drug scheduling module includes a drug management algorithm to forecast when a next refill of pump reservoir is required (para. 179, para. 207, and para. 318 of Lebel).

(F) Referring to claim 18, Lebel does not disclose wherein the appointment scheduling module is capable of contacting at least one entity for the appointment, wherein the entity is selected from the group consisting of a pharmacy, a caregiver, a physician, a hospital, and the patient.

Pilarczyk discloses wherein the appointment scheduling module is capable of contacting at least one entity for the appointment, wherein the entity is a pharmacy (col. 1, line 52 – col. 2, line 34 and col. 7, lines 19-54 of Pilarczyk)

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Pilarczyk within Lebel. The motivation for doing so would have been to automatically identify a refill date in order for replenishment to occur when the customer's supply of the drug runs out (col. 1, line 52 – col. 2, line 34 of Pilarczyk).

Insofar as the claim recites “the group consisting of,” it is immaterial whether or not the other elements are also disclosed.

(G) Referring to claims 19 and 20, Lebel discloses wherein the implantable drug delivery device is in communication with a computing device, the computing device operatively coupled to the entity (see Fig. 3 of Lebel).

Lebel does not disclose wherein the computing network is the Internet. However, at the time of the invention, it would have been obvious to a person of ordinary skill in the art to include a network such as the Internet in order to provide world wide access to the services provided by the system.

(H) Referring to claim 21, Lebel discloses an implantable drug delivery device, comprising (para. 204 and Fig. 3 of Lebel):

(a) a housing (para. 204 and Fig. 3 of Lebel);

(b) a drug reservoir carried in the housing configured to contain a therapeutic substance (para. 204 and Fig. 3 of Lebel);

(c) a flow control coupled to the drug reservoir for controlling the flow of the therapeutic substance from the drug reservoir through an infusion port (para. 204 and Fig. 3 of Lebel);

(d) electronics coupled to the flow control and a power source (para. 204 and Fig. 3 of Lebel);

(e) a telemetry module coupled to the electronics (para. 204 and Fig. 3 of Lebel);

(f) memory coupled to the electronics, the memory containing pump refill criteria and other refill criteria (para. 204, para. 179, para. 186, and Fig. 3 of Lebel);

(g) a monitoring module coupled to the memory and the electronics that monitors at least one pump operation variable (para. 204, para. 179, and para. 186 of Lebel);  
and,



(h) a refill module coupled to the memory and the electronic, the refill module configured to calculate at least one relationship among the pump refill criteria and monitored pump variables, the refill module configured to decide whether a pump refill activity should be reported, and the refill module configured to activate the telemetry module to report a refill activity, wherein the module is adapted to contact via the telemetry module a physician for the scheduling activity (para. 204, para. 179, para. 186, Fig. 3, para. 132, and para. 134 of Lebel).

Lebel does not expressly disclose the scheduling module configured to decide automatically and without scheduling input contemporaneously provided by the patient whether an appointment is required and to contact at least one entity for the appointment scheduling automatically, and without scheduling input contemporaneously provided by the patient.

Pilarczyk discloses the scheduling module configured to decide automatically and without scheduling input contemporaneously provided by the patient whether an appointment is required and to contact at least one entity for the appointment scheduling automatically, and without scheduling input contemporaneously provided by the patient (col. 1, line 52 – col. 2, line 34 and col. 6, lines 15-55 of Pilarczyk).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Pilarczyk within Lebel. The motivation for doing so would have been to automatically identify a refill date in order for

replenishment to occur when the customer's supply of the drug runs out (col. 1, line 52 – col. 2, line 34 of Pilarczyk).

Insofar as the claim recites “selected from the group consisting of,” it is immaterial whether or not the other elements are also disclosed.

(I) Referring to claim 22, Lebel discloses wherein the refill module determines whether an appointment is necessary to perform a pump refill (para. 179 and para. 186 of Lebel).

Insofar as the claim recites “the group consisting of,” it is immaterial whether or not the other elements are also disclosed.

(J) Referring to claim 23, Lebel discloses wherein the refill module communicates via the telemetry module with an external device (Fig. 3 of Lebel).

(K) Referring to claim 24, Lebel discloses contacting the patient via the telemetry module (para. 134 and Fig. 3 of Lebel).

Lebel does not disclose wherein the scheduling module contacts the patient for the appointment scheduling.

Pilarczyk discloses wherein the scheduling module contacts the patient for the appointment scheduling (col. 1, line 52 – col. 2, line 34 of Pilarczyk).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Pilarczyk within Lebel. The motivation for doing so would have been to automatically identify a refill date in order for

replenishment to occur when the customer's supply of the drug runs out (col. 1, line 52 – col. 2, line 34 of Pilarczyk).

(L) Claims 25 and 26 repeat the same limitations of claims 19 and 20, and are therefore rejected for the same reasons given for those claims.

(M) Referring to claim 39, Lebel does not disclose wherein the appointment scheduling module comprises a scheduling management algorithm capable of being enabled by the drug scheduling module to initiate the automatic scheduling of an appointment.

Pilarczyk discloses wherein the appointment scheduling module comprises a scheduling management algorithm capable of being enabled by the drug scheduling module to initiate the automatic scheduling of an appointment (col. 1, line 52 – col. 2, line 34 and col. 6, lines 15-55 of Pilarczyk).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Pilarczyk within Lebel. The motivation for doing so would have been to automatically identify a refill date in order for replenishment to occur when the customer's supply of the drug runs out (col. 1, line 52 – col. 2, line 34 of Pilarczyk).

(N) Claims 44 repeats the same limitations as claim 39, and is therefore rejected for the same reasons given above.

Claims 40-41 and 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al. (US 2002/0016568 A1) in view of Pilarczyk (4,766,542), and further in view of Mayer et al. (US 2002/0010597 A1).

(A) Referring to claim 40, Lebel and Pilarczyk do not disclose wherein the scheduling management algorithm receives predetermined scheduling preferences upon being enabled to initiate the automatic scheduling of an appointment.

Mayer discloses wherein the scheduling management algorithm receives predetermined scheduling preferences upon being enabled to initiate the automatic scheduling of an appointment (para. 50 and para. 16 of Mayer).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Mayer within Lebel and .Pilarczyk. The motivation for doing so would have been to take into consideration the availability of the patient (para. 50 of Mayer).

(B) Referring to claim 41, Lebel and Pilarczyk do not disclose wherein the predetermined preferences are holiday and work schedules.

Mayer discloses interacting with the patient's own calendaring system (para. 50 of Mayer).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Mayer within Lebel and Pilarczyk. The motivation for doing so would have been to take into consideration the availability of the patient (para. 50 of Mayer).

While Mayer does not mention holiday and work schedules, it would have been obvious to a person of ordinary skill in the art at the time of the invention, to include the aforementioned features since these are common events that would need to be worked around in order for a patient to attend an appointment.

Insofar as the claims recite "selected from the group consisting of," it is immaterial whether or not the other elements are also disclosed.

(C) Claims 45-46 repeat the same limitations as claims 40-41, and are therefore rejected for the same reasons given above.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al. (US 2002/0016568 A1) in view of Pilarczyk (4,766,542), and further in view of Akers et al. (6,112,182).

(A) Referring to claim 16, Lebel and Pilarczyk do not disclose wherein the drug scheduling module receives drug management data selected from the group consisting of name of drug manufacturer, date drug was manufactured, and name of pharmacy carrying the drug.

Akers discloses wherein the drug scheduling module receives drug management data such as name of drug manufacturer (col. 5, lines 18-21 of Akers).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Akers within Lebel and

Pilarczyk. The motivation for doing so would have been for a comprehensive drug record (col. 5, lines 18-21 of Akers).

Insofar as the claim recites “the group consisting of,” it is immaterial whether or not the other elements are also disclosed.

Claims 42-43 and 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al. (US 2002/0016568 A1) in view of Pilarczyk (4,766,542), and further in view of Cummings, Jr. et al. (US 6,345,260 B1).

(A) Referring to claim 42, Lebel and Pilarczyk do not disclose wherein the appointment scheduling module records whether all entities being scheduled have acknowledged acceptance of the scheduled appointment.

Cummings discloses wherein the appointment scheduling module records whether all entities being scheduled have acknowledged acceptance of the scheduled appointment (col. 8, lines 38-57 of Cummings).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Cummings within Lebel and Pilarczyk. The motivation for doing so would have been to provide a tentative booking confirmation of the appointment (col. 8, lines 38-57 of Cummings).

(B) Referring to claim 43, Lebel and Pilarczyk do not disclose wherein the appointment scheduling module searches for another appointment time in the event that not all entities being scheduled have acknowledged acceptance of the scheduled appointment.

Cummings discloses wherein the appointment scheduling module searches for another appointment time in the event that not all entities being scheduled have acknowledged acceptance of the scheduled appointment (col. 6, lines 16-18 of Cummings).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Cummings within Lebel and Pilarczyk. The motivation for doing so would have been to find other available appointment times and dates (col. 6, lines 16-18 of Cummings).

(C) Claims 47-48 repeat the same limitations as claims 42-43, and are therefore rejected for the same reasons given above.

#### **(10) Response to Argument**

In the Appeal Brief filed 24 March 2009, Appellant makes the following arguments:

A) Pilarczyk does not disclose or suggest an appointment scheduling module. There is no automatic scheduling of an appointment taught in Pilarczyk and the reminder is based only on an assumption that the medication was taken at the rate it was prescribed.

B) There would have been no reason for one of skill in the art to be motivated to provide an automatic scheduling module automatically initiated by a drug scheduling module, as recited in the instant claims, from the disclosures of Lebel and Pilarczyk.

Lebel states a concern for greater user involvement, thus the asserted disclosures actually teach away from eliminating user interaction by employing the novel automatic appointment scheduling as recited in the rejected claims.

C) Mayer, Akers, and Cummings, Jr. do not remedy the deficiencies of Lebel and Pilarczyk.

Examiner will address Appellant's arguments in sequence as they appear in the brief.

Argument A:

In response to Appellant's first argument, the Examiner respectfully submits that Pilarczyk discloses calculating a refill due date based on the prescription activity and storing records in a schedule file based on the calculated refill due date (see col. 6, lines 46-55 and col. 8, lines 35-50 of Pilarczyk). The Examiner interprets a "due date" to be a form of "appointment." As such, the broadest reasonable interpretation of an appointment scheduling module would include the automatic determination of when to replenish/refill a drug, which is disclosed in Pilarczyk.

Argument B:

In response to Appellant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by



combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Examiner respectfully submits that Pilarczyk was relied upon to teach automatic appointment scheduling and the motivation to combine the references came directly from the Pilarczyk reference.

#### Argument C:

In response to Appellant's argument that Mayer, Akers, and Cummings, Jr. do not teach eliminating user interaction, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

#### **(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Lena Najarian/

Examiner, Art Unit 3686

LN  
May 29, 2009

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Application: 10/002,669

Paper No. 20090529

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